Environmental Risk Characterization

DEP/LSPA Fall Training Seminar

Department of Environmental Protection

Today's Schedule

- Introduction

- Regulatory Goals - Defining the Questions to be Answered

- Stage I Screening Process

<---------- 15-Minute Break ---------->

- Stage II Environmental Risk Characterization

    - Scoping and Planning

<---------- 60-Minute Lunch Break ---------->

    - Collecting & Analysing Data
    - Drawing Conclusions

<---------- 20-Minute Break ---------->

- Small Discussion Groups

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Goals of Today's Seminar

- Introduce participants to Environmental Risk Characteriza
- Focus on concepts, vocabulary and issues
- Review MCP regulatory requirements

Based upon the MCP *and Chapter 9 of the* Guidance for
Disposal Site Risk Characterization *(March 1996)*

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Purpose of Environmental Risk Characterization under the MCP

- Derives from the definition of *Permanent Solution*

- "*Does contamination at a site pose a significant risk of harm to the environment?*"

- "*Is the site clean enough?*"

Purpose of Environmental Risk Characterization Guidance

- Outline BWSC Program Goals

- Identify Regulatory Objectives

- Provide framework for designing, conducting and interpreting assessments

- Indicate appropriate level-of-effort

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Applicability of MCP Environmental Risk Characterization Guidance

Applicable **only** to MCP sites and
those sites which may be considered "*adequately regulated*"
_if_ the requirements of Subpart I of the MCP are met.

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Why Look At Environmental Risk?

- Article 97 of the Massachusetts Constitution guarantees the people's right to "*clean air and water*", as well as "*the natural scenic, historic and aesthetic qualities of the environment.*"
- Environmental health affects human well-being
- "Natural resources have an intrinsic moral value that mus measured on its own terms and protected for its own sak
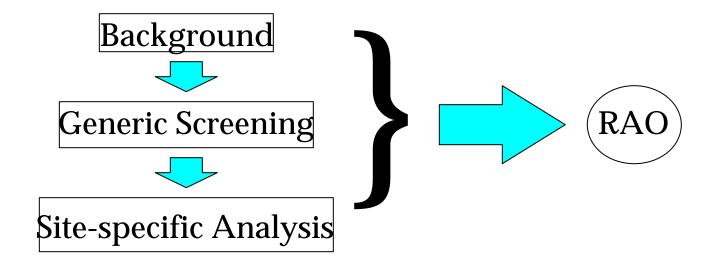- Recent passage of the Rivers Bill reinforces Massachusetts concern for environmental protection

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What is Significant Risk?

- *How Clean is Clean Enough?* is a value-laden question

- *What in the ecological world is worth preserving? At what cost? To Whom?*

- There is not the consensus there is in human-health risk management

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Significant Concepts for Significant Risk...

- Temporal variation

- Subtle effects of chemical contamination

- *Recovery*...What does it mean?

- Focus on individual animals? species? habitat?

- Significant Risk is *not* Certain Risk

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Overview of the Risk Assessment/ Risk Management Process

```
Background
   ↓
Generic Screening     }  ⟶  RAO
   ↓
Site-specific Analysis
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When are Environmental Risk Characterizations Required?

- 310 CMR 40.0942

- Method 3 may be used for **any** site

- Site Specific Environmental Risk Characterization

  is required when:

  ❶ Contamination is present in medium other than soil or groundwater

  ❷ Bioaccumulating chemicals present within 2 ft of the ground surface

Regulatory Goals of Environmental Risk Characterization

Defining the questions to be answered

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MCP Questions and Relevant Terms

- **v** Stage I Screening

- **v** Stage II Environmental Risk Characterization

- **v** Throughout the Environmental Risk Characterization Process

Stage I Environmental Screening

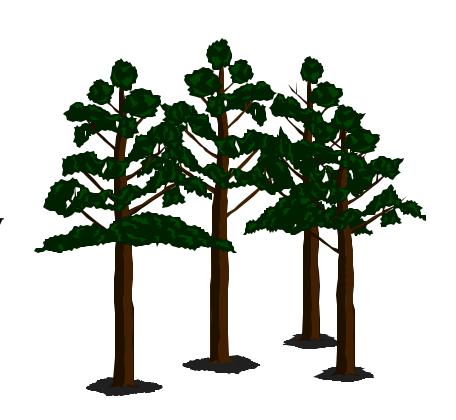- ❖ Characterize current and future exposures to environmental receptors

- ❖ Use identified screening approaches to determine if quantitative site-specific Stage II Environmental Risk Characterization is necessary

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Stage II Environmental Risk Characterization

v Stage II is a quantitative, site-specific characterization of the risk of harm to ecological receptors

v Ranges from simple to extensive

v Generally more complex and in depth than Stage I Screening step

Questions that need to be answered in Stage I to determine if a Stage II characterization is needed:

- v What complete exposure pathways exist?

- v Do those pathways represent "potentially significant exposures"?
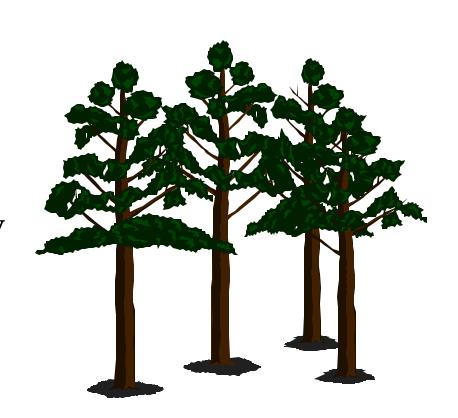
- v Is there readily apparent harm?

Definition of "Potentially Significant Exposure"

ᵥ Any potential exposure identified must be considered a "potentially significant exposure" unless it can be ruled out using an effects-based screening approach.

ᵥ Examples of screening criteria include:

① MA Surface Water Standards (310 CMR 4) - including USEPA AWQC

② literature values potentially associated with toxic effects

③ site size and location criteria specified by the Department

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(310 CMR 40.0995(3)(b))

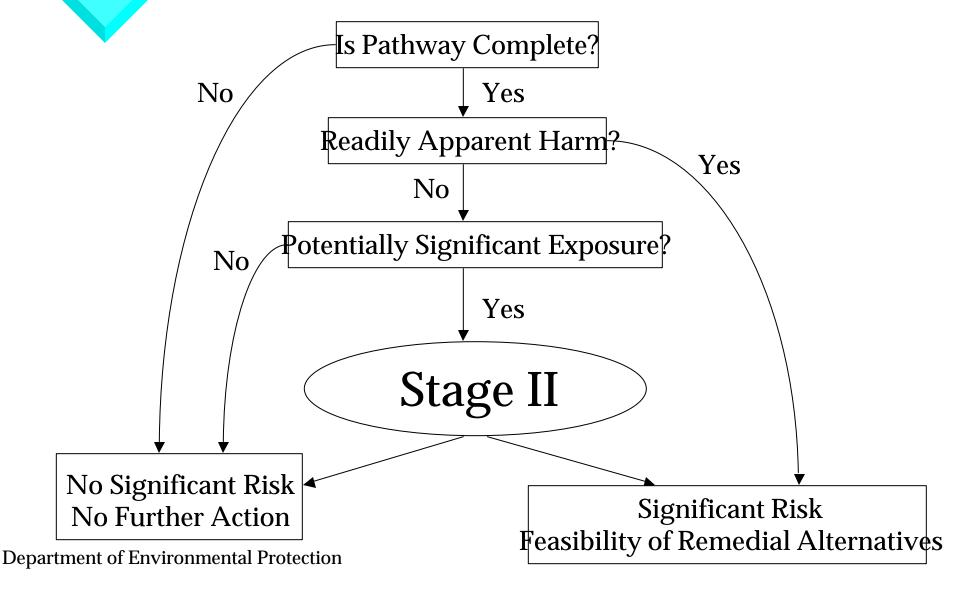## *Questions that need to be answered in Stage I to determine if a Stage II characterization is needed:*

ᵛ What complete exposure pathways exist?

ᵛ Do those pathways represent "potentially significant exposures"?

ᵛ Is there "readily apparent harm"?

Definition of "Readily Apparent Harm"

v   Visual evidence of stressed biota including fish kills or abiotic conditions.

v   OHM concentrations that exceed the MA Surface Water Quality Standards/USEPA Ambient Water Quality Criteria.

v   Visible presence of oil, tar, or other non-aqueous phase hazardous material

① in soil over an area equal to or greater than 2 acres,

② in sediment over an area equal to or greater than 1,000 ft^2

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(310 CMR 40.0995(3)(c))

Stage I Screening Outcomes

Is Pathway Complete?

No

Yes

Readily Apparent Harm?

Yes

No

Potentially Significant Exposure?

No

Yes

Stage II

No Significant Risk
No Further Action

Significant Risk
Feasibility of Remedial Alternatives

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Question that needs to be answered in a Stage II Environmental Risk Characterization

ᵛ Is there a "<u>Significant Risk of Harm</u>" to habitats and biota exposed to OHM at or from the site?

Is there "Significant Risk of Harm"?

- v There is "**No** Significant Risk of Harm"… ⟶ No further action

- v There is a "Significant Risk of Harm"… ⟶ Remedial action to reach level of NSR

- v There is a "Significant Risk of Harm"… ⟶ Possible Class C RAO if there is "No Substantial Hazard"

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Two questions that need to be considered throughout an Environmental Risk Characterization

v **Is there an Imminent Hazard?**

v **Is there a Substantial Release Migration?**

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Definition of an "Imminent Hazard"

v   IH definition for ***2-hour reporting purposes*** - a release to the environment of OHM which produces immediate or acute adverse impacts for freshwater or saltwater fish populations. (310 CMR 40.0321)

Definition of an "Imminent Hazard"

v   There is visible evidence of stressed biota attributable to the disposal site **or**

v   The risk characterization demonstrates that significant adverse ecological impacts are likely under current conditions and those impacts are likely to **persist** if current conditions were to remain unremediated for a short period of time. (310 CMR 40.0995)

For ecological risk assessments: ...are effects likely to **worsen** if conditions remain unremediated for even a short period of time ?

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Effects will be worsened over time by...

- v A decreased likelihood that the effects will be reversible.
- v An increase in the intensity of the exposure.
- v An increase in the extent of the exposure.
- v An increase in the toxicity of the exposure.
- v Exposure of additional receptors through food web transfers.

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Two questions that need to be considered throughout an Environmental Risk Characterization

v **Is there an Imminent Hazard?**

v **Is there a Substantial Release Migration?**

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Definition of "Substantial Release Migration"

ᵥ Evidence shows that a release of OHM has contaminated environmental media and the mechanism, rate, or extent of contaminant transport, if not promptly addressed, is likely to exacerbate release or site conditions and/or result in exposure/continued exposure of ecological populations to that OHM.

ᵥ Conditions of SRM include, but aren't limited to: releases resulting in the discharge of separate-phase oil and/or hazardous material to SW, releases to GW that have been or are within 1 year likely to be, detected in a SW body or wetland.

Department of Environmental Protection   (310 CMR 40.0410)
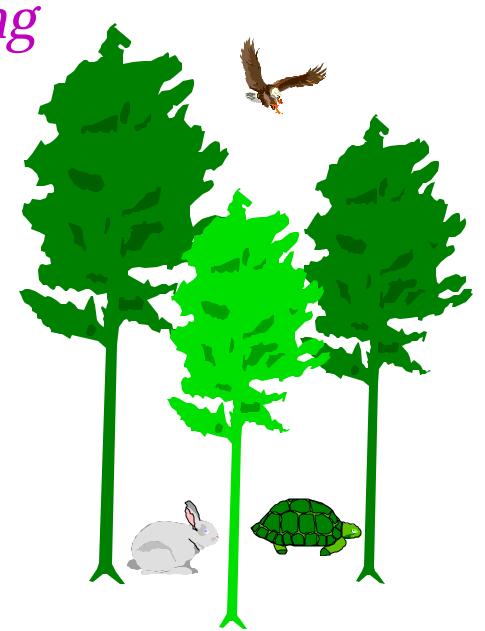
Environmental Risk Characterization

Stage I Screening

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Stage I Screening

❖ Aquatic

❖ Wetlands

ᵥ Terrestrial

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Aquatic Screening

v Surface Water

v Sediments

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Wetlands Screening

v Surface Water

v Sediments

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Terrestrial Screening

ᵛ Soil

Background
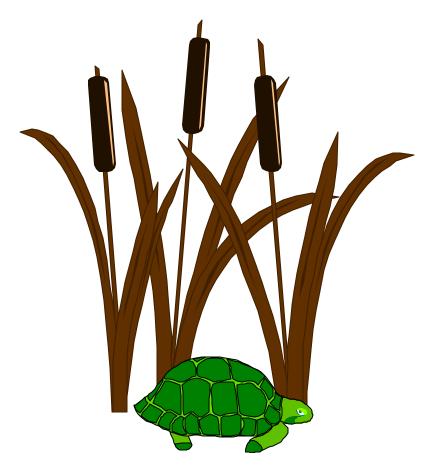
v   Those levels of oil and hazardous material that would exist in the absence of the disposal site of concern which are:

(a) ubiquitous and consistently present in the environment at and in the vicinity of the disposal site of concern; and

(b) attributable to geologic or ecologic conditions, atmospheric deposition of industrial process or engine emissions, fill materials containing wood or coal ash, releases to groundwater from a public supply system, and/or petroleum residues that are incidental to normal operation of motor vehicles.

(310 CMR 40.0006)

Data Requirements

📂 Adequacy of the data

📄 Sampling Considerations

Stage I Screening Steps

📂Identify complete Exposure Pathways

📄 Determine whether Readily Apparent Harm Exists (310 CMR 40.0995 (3)(b))

📄 Establish if Potentially Significant Exposures Exist (310 CMR 40.0995(3)(c))

Stage I Screening Outcomes

📂No Further Action

📄 No Further Study to Determine Significant Risk

📃 Stage II Environmental Risk Characterization

No Further Action

1 Eliminate from further evaluation because exposure pathways are incomplete (310 CMR 40.0995(2)(a)(1).

Eliminate from further evaluation because Potentially Significant Exposures do <u>not</u> exist (310 CMR 40.0995 (3)(c)(2)).
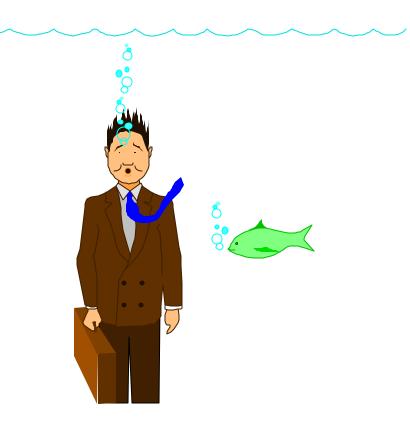
No Further Study to Determine Significant Risk

📂Further Study of that medium is <u>not</u> required because harm is Readily Apparent (310 CMR 40.0995(2)(b)(2)).

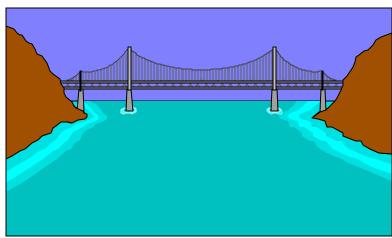📄 Evaluate Feasibility of achieving a level of No Significant Risk.

Stage II Risk Characterization

v Conduct a Stage II Environmental Risk Characterizatio n (310 CMR 30.0995(2)(a)(3))

Aquatic Habitats

- Are the Concentrations consistent with background?

- Are the Concentrations consistent with local conditions?

- Do complete exposure pathways exist?

- What are appropriate benchmark concentrations for Effects-Based Screening?

Background

- v Consistent with MCP definition (310 CMR 40.0006)
- v Identify a *reference area*
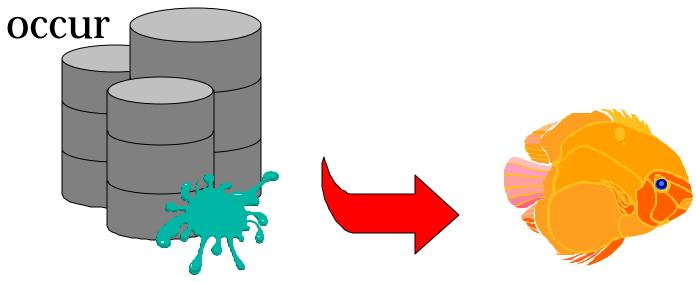
Local Conditions

v   Levels of oil or hazardous material present consistently and uniformly throughout a surface water body, or a large section of a river. Such conditions could be attributable to: contamination from other disposal sites, permitted discharges or non-point sources.

v   Identify a *reference area*

Complete Exposure Pathways

- v Contamination is present
- v Receptors are present
- v Exposure is occurring or is likely to occur

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Effects Based Screening

  v Effects based screening values are systematically derived sets of numbers, which are used by consensus, as values below which adverse effects on any valued entity are unlikely to occur.

  v One value should be used for each chemical.

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Surface Water Effects-Based Screening

v   Massachusetts Surface Water Standards (314 CMR 4.00) which include the USEPA Ambient Water Quality Criteria (AWQC)

   Use Chronic Values for marine or fresh water

v   EPA's Chronic Lowest Observed Effects Levels (LOELs)

v   Great Lakes Water Quality Initiative (GLWQI) Tier I and Tier II Values*

   * These values will be reviewed by ORS for use as screening values.

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Sediment Effect-Based Screening

v Effects Range-Low Values (ER-Ls)

v Ontario Ministry of Health Fresh Water Sediment Concentrations

v EPA Sediment Quality Criteria & Benchmarks*

* Use of values derived from an equilibrium partitioning approach is not generally recommended by DEP for screening purposes and should only be used as a last resort. Technical justification should be provided for the use of these values in a Stage I Screening.

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Wetlands Habitats

v Are contaminant concentrations consistent with background?

v Consider the habitat type
  – Submerged areas - use aquatic criteria
  – Upland/adjacent areas - use terrestrial criteria

Surface Water Effects-Based Screening

ᵛ Massachusetts Surface Water Standards (314 CMR 4.00) which include the USEPA Ambient Water Quality Criteria (AWQC)

   Use Chronic Values for marine or fresh water

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Terrestrial Habitats

v "Evaluation of Habitat Quality"

Evaluate the size of the affected terrestrial habitat, the extent it is connected to open land and the potential for effects on areas of special concern.

Terrestrial Habitats ≤ 2 Acres

- No Further Action <u>unless</u>:

  - State listed threatened or other species of special concern present; or

  - Contaminant transport from surface soil to Area of Critical Environmental Concern (ACEC) is possible

- If either of these criteria are tripped you must proceed with a Stage II Environmental Risk Characterization

Terrestrial Habitats ≥ 6 acres

v "Effects-based Screening"*; or

v Stage II Environmental Risk Characterization

* No values are currently available

Terrestrial Habitats >2 acres<6

- _v "Effects-based Screening"* or Stage II Environmental Risk Characterization; or
- _v Conduct further evaluation to determine the presence of significant exposure pathways:
    - □ adjacent to open land;
    - □ unique or unusual niche;
    - □ vernal pool within 150 meters;
    - □ habitat Massachusetts is restoring.
        * No values are currently available

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STAGE II ENVIRONMENTAL RISK CHARACTERIZATION

PLANNING

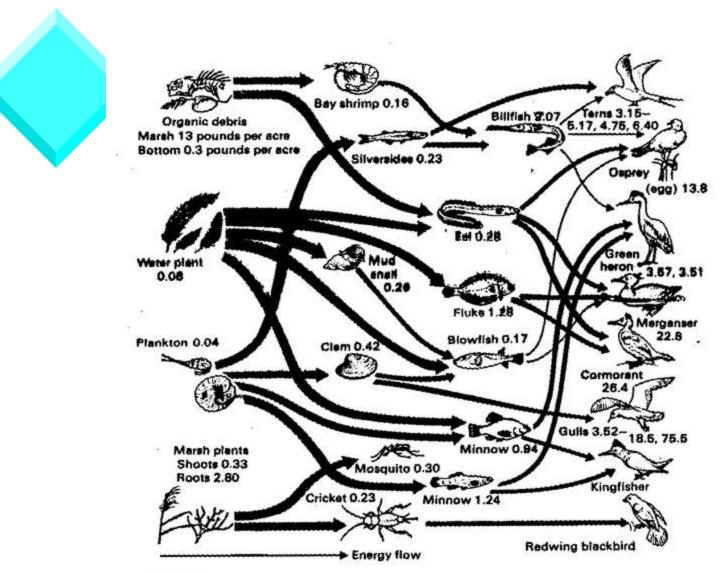Department of Environmental Protection

PLANNING A RISK ASSESSMENT

- v PLANNING (English version)
- v Decide what to evaluate
- v Decide how to evaluate it

- v PROBLEM FORMULATION (risk assessment terminology)
- v Select assessment endpoints
- v Chose measurement endpoints (or measures of effects)

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CONSEQUENCES OF PLANNING DECISIONS

- DECIDING WHAT TO EVALUATE
  - Determines meaning and value of the assessment
- DECIDING HOW TO EVALUATE IT
  - Determines the confidence/uncertainty about the conclusions

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FIGURE 7-1

Portion of a food web in a Long Island estuary. Arrows indicate flow of energy. Numbers are the parts per million of DDT found in each kind of organism. [After Woodwell, "Toxic Substances and Ecological Cycles." Copyright © 1967 by Scientific American, Inc. All rights reserved.]
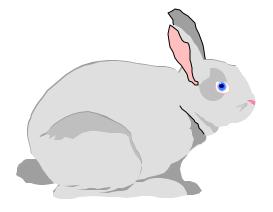
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EXAMPLES OF WHAT WE MIGHT EVALUATE

- Benthic invertebrate sub-populations or communities

- Fish sub-populations or communities

- Amphibian sub-populations

- Reptile sub-populations

- Bird sub-populations

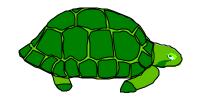- Individual organisms of a rare or endangered species

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DECIDING WHAT TO EVALUATE

v SUSCEPTIBILITY

v BIOLOGICAL RELEVANCE

v RELEVANCE TO PROGRAM OBJECTIVES

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SUSCEPTIBILITY

is the likelihood of an adverse effect resulting from a combination of exposure potential and sensitivity.

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BIOLOGICAL RELEVANCE

is determined by importance to a higher level of biological organization.
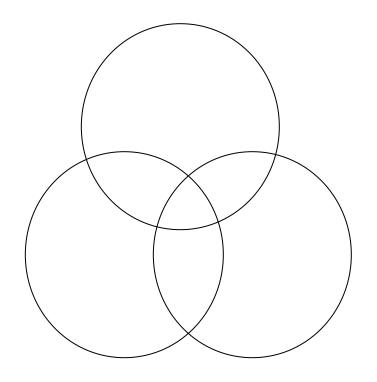
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RELEVANCE TO PROGRAM OBJECTIVES

means that the effect in question
is meaningful to DEP risk
managers and is valued by
EOEA.

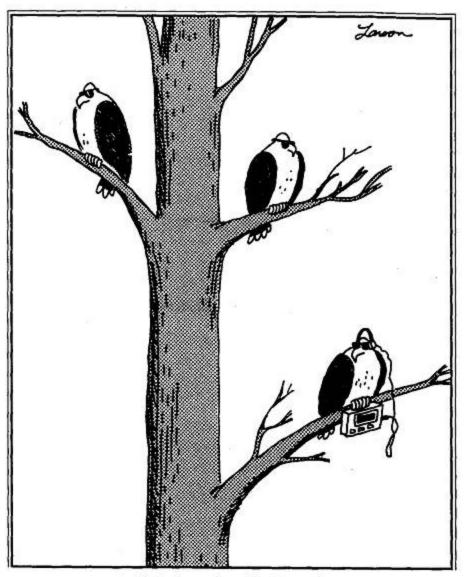Department of Environmental Protection

DECIDING WHAT TO EVALUATE

SUSCEPTIBILITY

BIOLOGICAL RELEVANCE

RELEVANCE TO THE REGULATORY PROGRAM

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Birds of prey know they're cool.

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DECIDING WHAT TO EVALUATE

SUSCEPTIBILITY

BIOLOGICAL RELEVANCE

RELEVANCE TO THE REGULATORY PROGRAM

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ASSESSMENT ENDPOINT STATEMENTS

- v BROADER
- v Sustainability of warm water fish species, including bottom feeders, forage fish feeding on invertebrates in the benthos, and piscivorous fish

- v NARROWER
- v Reduction in the blue gill population

HOW TO EVALUATE EFFECTS OF CONCERN

MEASURES OF EFFECTS

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MEASUREMENT METHODS

- Comparison to benchmark concentrations
- Comparison of estimated doses to doses associated with effects
- Toxicity tests or bioassays
- Field studies

DECIDING HOW TO MEASURE EFFECTS

- Consider the strengths and weaknesses of each measure: How closely linked is each measure with the effects/organisms being evaluated?

- Consider the nature and level of uncertainty: Given the decision at hand, is the uncertainty acceptable?

MEASUREMENT ATTRIBUTES

- Biological relationship between the measurement and the effect in question

- Correlation of stressor to response

- Sensitivity of the measurement endpoint

- Utility of the measure for judging environmental harm

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MEASUREMENT ATTRIBUTES (contd.)

- Data quality (expected)
- Site specificity
- Temporal and spatial representativeness
- Use of a standard method
- Sensitivity of the measurement
- Quantitativeness

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ASSESSMENT ENDPOINT (EXAMPLE)

Reduction in the population of bluegill

MEASUREMENTS (Example)

- v Benchmark comparisons - "Gold Book" values

- v Toxicity test - site sediment and surface water/commercial test organisms

- v Field study - compare population density and length/weight ratios with same from reference pond

It is often more important to do the right thing than to do the thing right.

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Environmental Risk Characterization

Collecting and Evaluating Data: Analysis

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Environmental Risk Characterization: Analysis

v **Collect and Integrate Data**

- – contaminant toxicity

- – contaminant concentrations

- – spatial distribution, patterns

- – observations/predictions of adverse effects

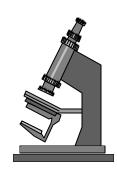v **Use Data to evaluate Measurements**

Overview of Topics

- v **Sampling**
- v **Analytical Issues - Surface Water**
- v **Analytical Issues - Sediment**
- v **Food Chain Exposures**
- v **Home Range Assumptions**
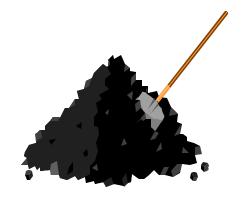
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Overview of Topics

v Sampling

- – Sample Number
- – Co-location of samples
- – Sample Depth

Sample Number

- Must adequately represent spatial and temporal variation in conditions
    - Surface Water: generally less variability, fewer samples needed
    - Sediment/Soil: generally more variability, more samples needed
- Uniformly distributed throughout the area of concern
- Sufficient Density to obtain representative data

Can Use statistics to determine number of samples needed

Sample Depth

- v Critical for obtaining data that accurately represents exposures to receptors
  - – for example, benthic and terrestrial invertebrates are more likely exposed to contaminants near surface
- v Sample collection equipment must allow differentiation between contaminant concentrations at various depths.

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Co-Location of Samples

v Samples should be collected at the same location and at the same time so data can be correlated

- chemical analyses (contaminant levels)
- physical analyses (e.g.. pH, hardness, organic carbon, particle size)
- biota

v **Lack of co-located samples may mean that data is not usable in the risk characterization!**

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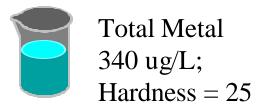
Overview of Topics

_v Analytical Issues - Surface Water

- Detection Limits
- Hardness and Dissolved Metals
- Other Physical Parameters

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Surface Water Analytical Issues: Detection Limits

v Typically must be quite low.

v Very low contaminant concentrations (especially metals) can pose a risk to aquatic organisms.

v Must be at least as low as EPA AWQS (for contaminants of concern).

Surface Water Analytical Issues
Why consider Hardness and Dissolved Metals?

CRITERIA

SAMPLE

Total AWQC
55 ug/L; Hardness =100

Hardness Adjustment

Total Metal
340 ug/L;
Hardness = 25
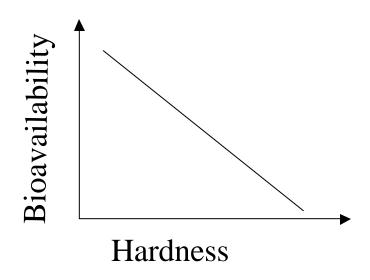
Total AWQC
17 ug/L; Hardness = 25

Dissolved Adjustment

Dissolved Metal
14 ug/L;
Hardness = 25

Dissolved AWQC
15 ug/L; Hardness = 25

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Surface Water Analytical Issues Hardness

v   Hardness is sum of Calcium and Magnesium concentrations, expressed as mg Calcium Carbonate per liter (mg/L $CaCO_3$).

Surface Water Analytical Issues Hardness

- v EPA AWQC for several metals are hardness dependent (Cd, CrIII, Cu, Pb, Ni, Ag, Zn).
- v EPA AWQC assume hardness of 100 mg/L $CaCO_3$.
- v Typical hardness in MA waters is much lower

   (25 mg/L $CaCO_3$).
- v AWQC should be adjusted for site-specific hardness, as appropriate.

Surface Water Analytical Issues Dissolved Metals

v Dissolved Metals (Filtrable metals): Metals in unacidified sample that pass through a 0.45 um membrane filter.

v Suspended Metals (nonfiltrable metals): Metals in an unacidified sample that are retained by a 0.45 um membrane filter.

v Total Metals: Dissolved + suspended fractions.

Surface Water Analytical Issues Dissolved Metals

ᵛ Dissolved metal concentrations should be used for comparison with water quality standards.

- more closely approximate bioavailable fraction of metal in water column

- primary mechanism for toxicity is adsorption at the gill surface

- toxicity of particulate metals much less than dissolved. However, high total metals could result in exposures via other pathways.

Surface Water Analytical Issues

EPA Equation for Calculating Dissolved Metals Water
Quality Criteria -- *For Metals that are NOT Hardness-Dependent*

Dissolved Criterion = Total Criterion * Conversion Factor

Example: Chromium VI

Dissolved Criterion = 10.80 ug/L * 0.962
Dissolved Criterion = 10 ug/L

Conversion Factor (CF) is the percentage of dissolved metals under test conditions .

CFs are provided in FRN Vol.60, No. 86, 5/4/95 (included in Handouts).

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Surface Water Analytical Issues

EPA Equation for Calculating Dissolved Water Quality
Criteria (for Hardness-Dependent Metals)

$$WQC_D = \exp^{(m\ [\ln\ hardness]\ +\ b)} * CF$$

WQC_D = Dissolved Water Quality Criterion
m = chemical-specific slope
b = chemical-specific y intercept
CF = conversion factor

EPA equation not valid for Hardness <25 mg/L or > 400 mg/L CaCO$_3$

Surface Water Analytical Issues

Comparison of Total and Dissolved Water Quality Criteria for Copper at different hardness levels.

Hardness	Total	Dissolved
100	12 ug/L	

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Surface Water Analytical Issues

Comparison of Total and Dissolved Water Quality Criteria for Copper at different hardness levels.

Hardness	Total	Dissolved
100	12 ug/L	11 ug/L

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Surface Water Analytical Issues

Comparison of Total and Dissolved Water Quality Criteria for Copper at different hardness levels.

Hardness	Total	Dissolved
100	12 ug/L	11 ug/L
25	3.6 ug/L	

Surface Water Analytical Issues

Comparison of Total and Dissolved Water Quality Criteria for Copper at different hardness levels.

Hardness	Total	Dissolved
100	12 ug/L	11 ug/L
25	3.6 ug/L	3.5 ug/L

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Surface Water Analytical Issues
Hardness and Dissolved Metals - Summary Points

v Compare dissolved metals site data with dissolved metals criteria; compare total metals site data with total metals criteria.

v Total metals criteria must be adjusted for site-specific hardness.

v Recommend collecting dissolved site data; dissolved metals at sites are often significantly lower than total metals.

v May be able to screen out Surface Water pathway
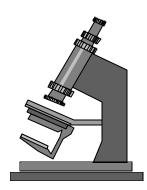
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Surface Water Analytical Issues Physical Parameters

- Many physical parameters may affect bioavailability of contaminants in surface water.
  - pH, alkalinity, salinity, ammonia, nutrients, dissolved oxygen, temperature, dissolved and suspended solids.
- Example - AWQC for pentachlorophenol is pH dependent (EPA assumes 7.8). Lower pH increases toxicity.
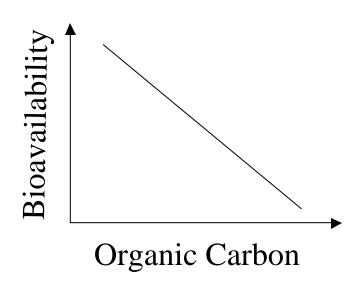
Overview of Topics

v **Analytical Issues - Sediment**

- Organic Carbon
- Acid-Volatile Sulfides (AVS)
- Other Physical Parameters

Analytical Issues: Sediment Organic Carbon

v Important indicator of bioavailability for nonionic organics (such as PCBs, PAHs).

v EPA Sediment Quality Criteria are valid above 0.2% organic carbon.

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Sediment Analytical Issues Organic Carbon

v Site-specific organic carbon can be used to generate sediment criteria that are protective of aquatic life.

v Using EPA equilibrium partitioning approach, a contaminant level in sediment can be calculated which predicts contaminant levels in pore water due to partitioning from sediment to water.

Sediment Analytical Issues Organic Carbon

Equation for calculating sediment levels that are protective of aquatic life.

$$SQB = K_{oc} * f_{oc} * WQC$$

SQB = Sediment Quality Benchmark; ug/kg
K_{oc} = Organic Carbon Partitioning Coefficient; L/kg
f_{oc} = Fraction of organic carbon in sediment; kg/kg
WQC = Water Quality Criterion; ug/L

Sediment Analytical Issues Acid-Volatile Sulfides

v Acid-Volatile Sulfides (AVS) important in binding some metals, reducing toxicity.

v AVS-Simultaneously extracted metals ratio is useful in evaluating bioavailability of inorganics in sediments.

v AVS can be used to interpret toxicity tests

Sediment Analytical Issues Physical Parameters

v Many physical parameters may affect bioavailability of contaminants in sediment (for example, grain size, pH, temperature).

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Food Chain Exposures

v Toxic effects in food chain expected only for substances that bioaccumulate

- substances known to bioaccumulate include mercury, cadmium, PCBs, pesticides.

v Food chain model only appropriate for those substances that bioaccumulate.

Home Range Assumptions

v Home range is the geographic area encompassed by an animal's activities (excluding migration).

v Home range is often much larger than site size.

v Fraction of home range that is comprised by the site size does not necessarily equate to the fraction of exposure that occurs at the site.

v Animals may preferentially visit site because of good habitat or food sources.

Environmental Risk Characterization

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Risk Characterization

The objective of an MCP Environmental Risk Characterization is to characterize the *risk of harm to habitats and biota exposed to OHM.*

Risk of Harm - not <u>Proof</u> of Harm

Habitats and Biota Exposed to OHM - The spatial scale of the assessment should match that of the disposal site.

Risk Characterization

- Compare Site Conditions to Any Applicable or Suitably Analogous Standards (310 CMR 40.0993(3))

- Determine Whether or Not a Level of No Significant Risk Exists or Has Been Achieved (310 CMR 40.0995(4)(d))

- Compare Site Concentrations in Soil and Groundwater to Upper Concentration Limits (310 CMR 40.0995(5))

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Applicable of Suitably Analogous Standards *(310 CMR 40.0993(3))*

Detailed Discussion is provided is Section 9.7 of the Guidance for Disposal Site Risk Characterization

- Massachusetts Surface Water Quality Standards

  (310 CMR 4.00)

- Massachusetts Wetlands Regulations

  (310 CMR 10)

No Significant Risk
(310 CMR 40.0995(4)(d))

- ## No Continuing Release of OHM
  (301 CMR 40.0995(4)(d)1.)

- ## Concentrations of OHM Less Than MA SWQS
  (301 CMR 40.0995(4)(d)3.)

- ## No Evidence of Biologically Significant Harm
  (310 CMR 40.0995(4)(d)2.)

- ## No Potential for Biologically Significant Harm
  (301 CMR 40.0995(4)(d)4.)

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Is There Significant Risk?

Measured results are evaluated to determine if they support a conclusion that a level of no significant risk of harm to the environment exists or has been achieved, *for each assessment endpoint.*

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Risk Characterization - Possible Results

- For each assessment endpoint, the measured results are clear and unambiguous. An evaluation of all assessment endpoints indicates that a condition of no significant risk has/has not been achieved.

- For one (or more) assessment endpoint, the measured results are ambiguous and/or contradictory. It is not clear what conclusion can be drawn from these results.

Consider the Weight-of-Evidence

Consideration is given to the strengths and weaknesses of the results of each measurement endpoint to draw a conclusion about an assessment endpoint.

Guidance for Disposal Site Risk Characterization, Section 9.3.2.2

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Considerations When Determining the Weight-of-Evidence

1 Weight given to each measurement endpoint

2 Results of the measure

3 Strength of that result

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1. Relative Weight of Measurement Endpoints

- Strength of association between the measurement endpoint and the assessment endpoint (high, medium, low)

- Quality of the Study Design (high, medium, low)

- Data Quality (pass, fail)

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2. *Results of Each Measure* and 3. *Strength of the Result*

- Positive, indication of risk *(Strong or Weak)*
- Negative, no indication of risk *(Strong or Weak)*
- Indeterminate *(Strong or Weak)*

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ASSESSMENT ENDPOINT (EXAMPLE)

Reduction in the population of bluegill

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MEASUREMENTS (Example)

ᵥ Benchmark comparisons - "Gold Book" values

ᵥ Toxicity test - site sediment and surface water/commercial test organisms

ᵥ Field study - compare population density and length/weight ratios with same from reference pond

RESULTS OF MEASUREMENT 1

BENCHMARK COMPARISONS - "GOLD BOOK" VALUES

- v Site surface water conc. = 5 ug/L
- v Freshwater chronic value, may not be protective of extremely sensitive species, = 0.66 ug/L

Weight Assigned: *Moderate*

RESULTS OF MEASUREMENT 2

TOXICITY TEST USING SURFACE WATER AND SEDIMENT FROM THE SITE AND COMMERCIAL TEST ORGANSIMS (BLUE GILL SUNFISH)

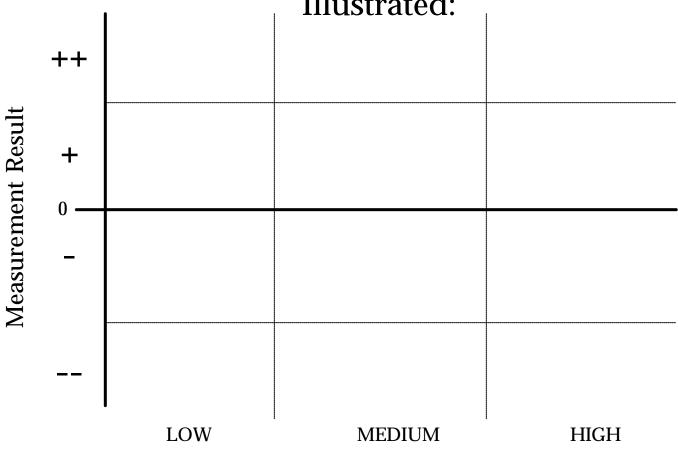v Statistically significant difference in mortality after 96 hours

Weight Assigned: *High*
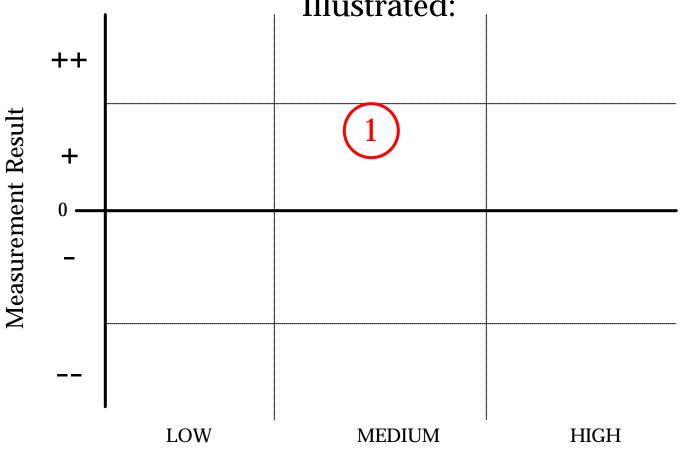
RESULTS OF MEASUREMENT 3

ᵛ FIELD STUDY - COMPARISON OF POPULATION DENSITY AND LENGTH/WEIGHT RATIOS WITH SAME METRICS FOR REFERENCE AREA

ᵛ Density in contaminated area is lower but not statistically significant

ᵛ Length/age ratios generally lower in contaminated area
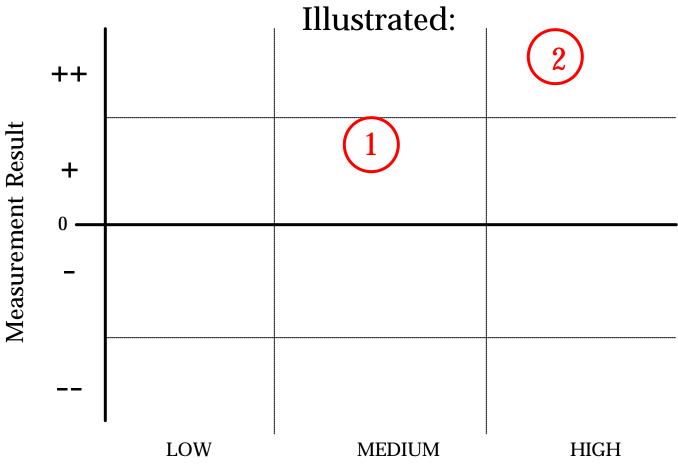
Weight Assigned: *Low*

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The 3 Considerations May Be Graphically Illustrated:

Y-axis: Measurement Result (++, +, 0, -, --)

X-axis: Relative Weight of Measurement Endpoint (LOW, MEDIUM, HIGH)
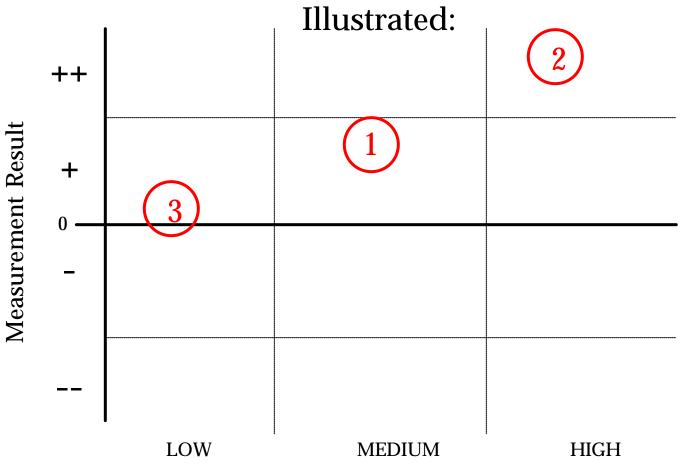
The 3 Considerations May Be Graphically Illustrated:

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The 3 Considerations May Be Graphically Illustrated:

Risk Management

- Is there an Imminent Hazard?

- Does a level of No Significant Risk exist or has it been achieved?

  If No,

  - Is remediation technically and economically feasible?
  - What is the most appropriate technology for cleanup and/or exposure mitigation?
  - How quickly must remediation be done to protect health and the environment?

Upper Concentration Limits

- Exceedance of an UCL indicates significant *future* risk of harm to the environment.

    While not directly tied to a specific endpoint, the UCLs are management tools used to identify gross contamination which is not consistent with the statutory, regulatory or common understanding of a *Permanent Solution* for a contaminated site.

Goals of Today's Seminar/ What We Accomplished

- ✓ Introduce participants to Environmental Risk Characterizat

- ✓ Focus on concepts, vocabulary and issues

- ✓ Review MCP regulatory requirements

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